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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,557	08/22/2001	Erik Gunther	GUNE117293	8854

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,557	GUNTHER, ERIK	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *5,12-17 and 22-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-9,18-21,32 and 34-37* is/are rejected.

7)☒ Claim(s) *3,10,11 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' response, filed 12 September 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-37 are currently pending. Claims 1-4, 6-11, 18-21, and 32-37 are hereby examined, as they are drawn to the elected species. Claims 5, 12-17, and 22-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 October 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 4, 6-9, 18-21, and 32, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,368,794 (Daniel et al.) in view of Marton et al. (Nature Medicine (1998) Vol. 4, No. 11, pages 1293-1301.

Daniel et al. teach steps (a) and (b) of instant claim 1 in column 10, lines 5-67. In column 10, lines 5-20, the determining of gene expression profiles wherein differing levels of expression are detected and quantitated is set forth. In column 10, lines 54-67, hybridization complexes are described for such determinations wherein a standard value (first expression profile of step a) of instant claim 1) for each signal is discussed which is altered compared to said standard in a disease state which is the second sample profiling practice of step b) of instant claim 1. Column 10, lines 64-67, begins a discussion of utilizing such assays for evaluating the efficacy of a therapeutic regimen. In column 11, lines 1-7, this evaluation practice is clarified in that a treatment protocol is initiated and hybridization assays are repeated to "determine if the level of expression in the patient begins to approximate that which is observed in a healthy subject". Such comparisons are also reasonably a difference profile determination as in instant claim 2. Such repeated assays of expression levels after treatment is reasonably step (c) of instant claim 1 when considered in view of what is meant in Daniel et al. regarding treatment.

Daniel et al. goes on to state that the results may be used to show the efficacy of treatment over time. The approximation of assay level outcome to a healthy subject is reasonably interpreted as accurately suggesting and motivating step (d) of claim 1 wherein efficacy of treatment causes the expression level to return to the first profile of a healthy subject. Daniel et al. describes what is meant therein for treatment as several citations including column 2, line 65, through column 3, line 5, which is clearly an analyte as instantly utilized in step (c) of instant claim 1 . In column 5, lines 27-42, the sequences that may be selected for pharmaceutical compositions are first selected from differentially expressed genes in cancerous or precancerous tissue and thus are uncharacterized at that point as to whether they have any specific pharmacological activity as also a limitation in instant claim 1, step (c).

Daniel does not specifically teach "at least one analyte of previously uncharacterized specific pharmacological activity with respect to the parameter by which the first and the second samples are known to differ". However, Marton et al, teach a method of drug target validation and identification of secondary drug target effects based upon genome wide expression patterns (abstract). Specifically. Marton teaches a method that permits the direct confirmation of drug targets and recognition of drug-dependent changes in gene expression that are modulated through pathways distinct form the drug's intended target (abstract). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the method of identifying"previously uncharacterized drug activity" of Marton in the methods of Daniel. One would have been motivated to do so because Marton states that expression arrays can be refined to increase the reliability of the data and permit new applications. For example, subtle gene signatures can be detected.

Conclusion

Claims 3, 10, 11, and 33 are objected to for being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

The prior art does not teach or fairly suggest comparing, using a neural network, a third expression profile with a first and second expression profile to identify one or more analytes that induces a third expression profile that is more similar to the first expression profile than is a second expression profile. Further, the prior art does not teach or fairly suggest the method steps wherein one of the expression profiles is determined by simultaneously detecting rates of transcription.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 12, 2005
Lori A. Clow, Ph.D.
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

12/12/05